

## Declaration of Conformity

**Manufacturer:** HPC Healthline UK Limited, Colwood House,  
158 Garth Road, Morden, Surrey, SM4 4LZ, UK.

**Product:** GS641 Sterile Co-Polymer Paper Backed Over Glove

**Brand Name:** HandSafe

**Classification:** Class I Sterile (According to Annex IX, Rule 5 of Council Directive 93/42/EEC, as amended by directive 2007/47/EC).

**Conformity Assessment Route:** ANNEX V: Product Quality Assurance

**Harmonised Standards:** Medical gloves for single use:

- BS EN 455-1 Freedom from Holes
- BS EN 455-3 Biological Evaluation

Sterilisation of Healthcare Products

- BS EN ISO 11137 series of standards

HPC Healthline UK Limited hereby declares that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for Medical devices, as amended by directive 2007/47/EC and requirements of BS EN 455-1, BS EN 455-3 and the BS EN ISO 11137 series of standards.

**Signature:**



**Name:** David Greenwood

**Place of Issue:** Morden, UK

**Position:** Director

**Date:** 29<sup>th</sup> November 2016

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